

### REMARKS

Claim 30 is cancelled and claims 27-29, 31, 33, and 41-54 are pending herein. Claims 27 and 28 are amended by replacing the term “intact” with the synonymous term “non-disrupted,” as discussed below. The specification provides basis for this amendment on page 14, lines 9-17, page 5, lines 6-7, and page 6, lines 10-17, and therefore, no new matter has been added.

#### “Consisting Essentially Of”

Claims 27, 28, and 54 include the language “consisting essentially of,” which is objected to in the Office action as the claims allegedly cover cells that are alive. The Office action cites *In re Herz* and states that the prior art in that case disclosed a composition having the same basic and novel characteristics as the claimed subject matter at issue therein. The Office action also cites *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.* and other cases that hold there are circumstances in which steps in a process claim may distinguish the resulting product from prior art products and that it is Applicant’s burden in such a situation to show that the introduction of additional steps or components would not materially change the characteristics of Applicant’s invention.

*In re Herz*, *Atlas Powder Co.* and related cases do not apply to the pending claims because the claimed products do not have “the same basic and novel characteristics” and are distinct over the products disclosed in the cited documents. As described below, the cited documents fail to disclose or suggest granules of dead microorganisms, which are limitations in each pending claim. Moreover, claim 54 is further limited to dried granules. Furthermore, because the claims contain the limitation “dead,” the claims do not cover compositions having a significant number of cells that are alive. Hence, the language “consisting essentially of” is proper and it is respectfully requested that the rejections of the claims set forth below be withdrawn.

#### Rejection of Claims Under 35 U.S.C. §112, First Paragraph

Claims 27-31, 33, and 41-53 were rejected under 35 U.S.C. §112, first paragraph, for an alleged lack of written description of granulated cells that are both intact and dead. The rejection was respectfully traversed in the Response to the Final Office Action as the specification clearly describes granules of intact cells prepared by extrusion methods that minimize destruction of cells and optimize the number of intact cells (page 6, lines 10-17), and methods of heat treating fermentation broths prior to granulation that result in killing the microorganisms and inactivating enzyme activity (page 10, lines 15-26). Also, the Bijl Declaration filed with the Response to the Final Office Action demonstrates that the specification teaches granulated cells that are both intact and dead. A copy of the Bijl Declaration is attached herewith as Exhibit B. The Advisory Action did not discuss this rejection presumably because the rejection had been overcome by the reasoning set forth in the Response to the Final Office Action. Accordingly, it is respectfully requested that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn since the specification provides a clear written description of the claimed subject matter.

#### Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

In the Advisory Action mailed 23 January 2001, it was stated that use of the term "intact" was repugnant to the art-recognized meaning and therefore could not be accepted. The rejection is moot in view of the amendment to claims 27 and 28 because the term "intact" has been replaced with the term "non-disrupted." As noted above, the term "non-disrupted" finds basis in the specification on page 14, lines 9-17, page 5, lines 7-9, and page 6, lines 10-17, as the specification states that extrusion conditions may be selected to minimize cell disruption and optimize the number of cells that remain intact. The term "non-disrupted" is synonymous with the term "intact" and is well understood by the skilled artisan, as the latter is defined in

Webster's Unabridged Dictionary as "not altered" and "not broken." See copy of definition for "intact" in Exhibit C. Hence, the term "non-disrupted" is definite.

In the Final Office Action, it was alleged that the terms "granulate formed by extrusion which consists essentially of dead intact microorganisms or dead microbial cells" and solvent access "via the pores" were indefinite. The Response to the Final Office Action demonstrated that each of these terms were definite and the Advisory Action did not refute this conclusion.

Accordingly, it is respectfully requested that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn as the terms "non-disrupted," "granulate formed by extrusion which consists essentially of dead intact microorganisms or dead microbial cells," and solvent access "via the pores" are definite.

#### Rejection of Claims Over Rhodes *et al.*, Huang *et al.*, and Cockram *et al.*

Claims 28-31 and 33 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Rhodes *et al.*, or alternatively, the claims are rejected under 35 U.S.C. §103 as allegedly obvious over the same document. Also, claims 27-31, 33 and 41 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Huang *et al.* or Cockram *et al.*, or alternatively, the claims are rejected under 35 U.S.C. §103 as allegedly obvious over the same documents. Applicant respectfully traverses the rejections.

#### Rhodes *et al.*

Claims 28-31, 33, and 54 are directed to granules of dead microorganisms. The specification states that microorganisms may be killed by pasteurization, for example, which provides an advantage of inactivating one or more enzymes that may adversely affect compounds extracted from the granules (page 10, line 15 to page 11, line 5).

In contrast to the claimed subject matter, Rhodes discusses compositions having a pesticidally active amount of a fungal control agent where the agent is present in the form of blastospores. The blastospores are not dead as they may actively proliferate and establish

populations in soil samples (column 6, lines 48-51) and act as an insecticide (table 10 at column 10). Accordingly, Rhodes does not anticipate claims 28-31 and 33 because the document fails to disclose granules of dead microorganisms, and it is respectfully requested that the rejection under 35 U.S.C. §102 over Rhodes be withdrawn.

Moreover, the claims are not obvious over Rhodes because there is no motivation for modifying the document so that it extends to dead microorganisms. The document in fact teaches away from dead microorganisms because the object of the disclosed invention is to provide a composition comprising a pesticidally active amount of fungal blastospores that may proliferate in soil and eradicate populations of the *Diabrotica balteata* (column 2, lines 22-25). The blastospores would not meet the stated objects of the Rhodes invention if they were dead because they would have no way of propagating and acting as a pesticide. Therefore, Rhodes teaches away from dead microorganisms because only live microorganisms can act as a pesticide. Accordingly, there is no motivation to modify Rhodes to cover the claimed subject matter, and it is respectfully requested that the rejection of the claims under 35 U.S.C. §103 over Rhodes be withdrawn.

Cockram et al. and Huang et al.

As noted above, claims 27-31, 33, and 41 are directed to granules of dead microorganisms, as the invention is in part directed to the discovery that certain granulated microorganisms are optimal for use in solvent extraction methods. The specification teaches a number of methods for preparing granulated microorganisms (page 13, line 25 to page 20, line 10), and addresses a number of variables important in processes for forming granules of proper size for use in solvent extraction. In particular, it is noted that temperature of the biomass has been found to influence production of the granular particles produced upon extrusion (page 14, lines 21-22).

The specification also addresses several advantages imparted by the granules. Specifically, when products are being extracted from the granulated microorganisms, the granules do not clog filters used in the extraction process as compared to products that are milled, flaked or comminuted (page 4, lines 28-32), and the granules are free-flowing and are easily packed and poured (page 19, line 27 to page 20, line 8). Furthermore, the granules are readily dried, which imparts a long shelf-life at room temperature and facilitates solvent extraction because a reduced amount of solvent is required for extraction (page 20, lines 24-25 and page 21, lines 26-27).

In contrast to the granulated microorganisms of the claims, Cockram and Huang discuss methods for preparing fungal cultures into a product having a texture analogous to meat, fish, or other conventional textured food stuffs. It is made clear in these documents that the filamentous nature of the fungal material imparts the desired texture of the meat substitutes. For example, Cockram goes to great lengths to describe the filamentous structure of the textured mycelial fungal mass (column 2, line 64 to column 3, line 4). Similarly, Huang states that the meat-like texture of the products is due to an entangled mass of limp flexible mycelial filaments having large areas of surface contact, and rapid heat setting of these contacts increases the strength of the product for a marked increase in cookability and chewability (column 2, lines 45-59). Hence, Cockram and Huang discuss filamentous meat substitutes that can be chewed and do not disclose granules of microorganisms suitable for use in solvent extraction.

Although Cockram discusses methods of chopping extrudates into smaller "chunks" (Cockram at column 3, line 41 to column 4, line 1) and Huang discusses heat-setting energies for use with long extrudates having smaller cross sections (column 4, lines 14-42), the documents do not once refer to the products as "granules." Furthermore, the documents do not disclose the variables addressed in the present specification that are required for producing granules, such as optimal temperatures for obtaining granules of a particular size. This deficiency is likely because the stated invention in the documents is a method for preparing fibrous and chewable

products that resemble chunks of meat, and not free-flowing granules that may be easily packed and poured for eventual use in solvent extraction processes. Thus, because Cockram and Huang do not disclose granules of microorganisms, it is respectfully requested that the rejection of claims 27-31, 33 and 41 under 35 U.S.C. §102 be withdrawn.

Moreover, the claims are not obvious over Cockram and Huang because there is no motivation for modifying the documents so that they extend to granules of microorganisms. The documents discuss fibrous meat substitutes and the Court of Appeals for the Federal Circuit has held that there is no proper motivation to modify a document to cover the claimed subject matter when the prior art does not teach the utility asserted for the claimed subject matter. *In re Lahu*, 747 F.2d 703, 707, 223 USPQ 1257, 1260 (Fed. Cir. 1984). Because the documents do not appreciate the use of granulated microorganisms in solvent extraction methods, the documents did not envision and therefore did not teach the claimed granules pursuant to the holding in *In re Lahu*.

Furthermore, it is well settled that the requisite motivation must come from the prior art and not Applicant's specification. *See In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ 2d 1529, 1531-1532 (Fed. Cir. 1988). As noted above, it is the specification that teaches variables important for the production of granules (e.g., temperature for extrusion), not the cited documents, since the documents discuss parameters optimized for producing texturized meat substitutes and not granules.

Hence, there is no motivation to modify either Huang or Cockram because the documents do not teach the asserted utility of the granules and the documents could only result in the claimed granules if their teachings are impermissibly combined with what is taught in Applicant's specification. Accordingly, it is respectfully requested that the rejection of the claims under 35 U.S.C. §103 over Huang and Cockram be withdrawn.

Rejection of Claims Under 35 U.S.C. §103 In View Of Akimoto *et al.*

Claims 42-49 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Huang or Cockram or Rhodes in view of Akimoto. The rejection is respectfully traversed.

Akimoto discusses a process for purifying bishomo- $\gamma$ -linolenic acid. The document discusses a process in which microorganisms are cultured, collected from the culture broth, dried by lyophilization or air-drying, and then extracted with an organic solvent. The document does not disclose or suggest a process for granulating the cells, nor a process for killing the cells.

As described above, there is no motivation to combine Akimoto with Rhodes since Rhodes teaches away from the claimed dead microorganisms. And even if the documents could be combined, the combination does not result in the claimed subject matter because neither of the documents disclose or suggest the production of dead microorganisms. Furthermore, as noted above, Akimoto may not be properly combined with Cockram and Huang because Cockram and Huang in particular fail to suggest the claimed granules. Also, even if the documents were properly combined, the combination of Akimoto with Huang or Cockram does not result in the claimed subject matter because none of the documents disclose or suggest granulated microorganisms. Accordingly, it is respectfully requested that the rejection of claims 42-49 under 35 U.S.C. §103 in view of Akimoto be withdrawn as there is no proper motivation to combine Akimoto with any of the primary documents, and the combination of Akimoto and those documents does not result in the claimed subject matter.

Rejection of claims under 35 U.S.C. §103 in view of Casey *et al.*

Claims 50-51 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Rhodes or Huang or Cockram in view of Casey. The rejection is respectfully traversed.

Casey discusses a process for preparing tetraacetylphytosphingosine (TAPS) using an F-60-10 mating type strain of *Pichia ciferrii*, including the steps of establishing a culture of *P. ciferrii*, separating the microorganism from the culture broth, drying the microorganisms

overnight at 110° C, and extracting dried cells with a 4:1 mixture of ethyl acetate and methanol. The document, however, does not disclose a process for granulating microorganisms and it is not clear whether Casey's process kills the cells.

If Casey does not kill the cells, the combination of Rhodes with Casey does not result in the claimed dead cells. In the alternative, if it were determined that Casey's process kills the cells, there is no proper motivation to combine Casey with Rhodes because the proposed modification of Rhodes would destroy the intended function of the blastospores described therein. See *In re Fritch*, 972 F. 2d 1260, 1265, 23 USPQ.2d 1780, 1783 (Fed. Cir. 1992), where the Court of Appeals for the Federal Circuit found that a proposed modification is inappropriate for an obviousness inquiry when the modification renders the prior art reference inoperable for its intended purpose. Because killing the blastospores in Rhodes would not yield a composition that could proliferate in soil and eradicate insects, there is no motivation to combine Rhodes with Casey.

Furthermore, Casey does not result in the claimed subject matter when combined with Huang or Cockram, because none of the documents disclose or suggest granules of microorganisms. Also, as discussed above, there is no motivation to combine Huang or Cockram with Casey. Therefore, it is respectfully requested that the rejection of claims 50-51 under 35 U.S.C. §103 in view of Casey be withdrawn, as the combination of the cited documents does not result in the claimed subject matter and Casey is not properly combined with the cited primary documents.

Rejection of claims under 35 U.S.C. §103 in view of Rickes *et al*

Claims 52-53 are rejected under 35 U.S.C. §103 as allegedly being unpatentable over Rhodes or Cockram or Huang in view of Rickes. The rejection is respectfully traversed.

Rickes discusses methods for culturing fungi for the purpose of producing vitamin B<sub>12</sub> concentrates, which include steps of culturing the fungi, separating the fungi from fermentation

broths by filtration, and then spray drying or freeze drying the resulting cells. The document does not disclose or suggest processes for granulating the fungi or for killing the fungi.

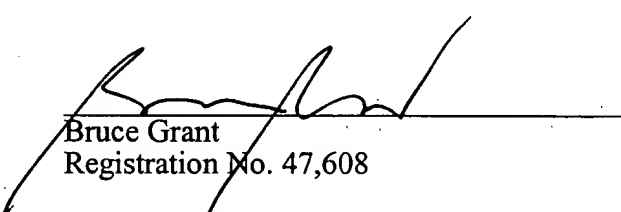
As noted above, there is no motivation to combine Rhodes or Cockram or Huang with Rickes. In addition, the combination of Rhodes and Rickes does not result in dead microorganisms, as Rickes does not disclose or suggest a method for killing the cultured fungi. In addition, the combination of Cockram or Huang with Rickes does not result in granulated microorganisms because spray drying and freeze drying of the fungi do not yield granules (see specification on page 17, line 3 to page 18, line 13, stating that spray drying yields a powder that must be further processed to yield granules). Thus, there is no motivation to combine Rickes with the other cited documents and the combination of Rickes with those documents does not result in the claimed subject matter. Accordingly, it is respectfully requested that the rejection of claims 52-53 under 35 U.S.C. §103 in view of Rickes be withdrawn.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 251502006900.

However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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**EXHIBIT A: VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

27. (Six times amended) A porous free-flowing [fungal] microbial granulate formed by extrusion, which consists essentially of [intact] non-disrupted dead microorganisms [or dead microbial cells] obtained by mechanical extrusion of a microbial biomass, the granulate having a structure that allows a solvent access, via the pores, to the [intact] dead cells to isolate or extract a compound therefrom.

28. (Five times amended) A composition consisting essentially of granular particles of [intact] non-disrupted dead microbial cells from a biomass, which particles

- (a) are obtained by granulating the biomass having a dry matter content of 25 to 80%;
- (b) have a dry matter content of at least 30% but less than 70%; and
- (c) have a structure that on drying allows isolation or extraction of a desired compound from the [intact] dead cells with a solvent through pores and/or channels.

31. (Amended) A composition according to claim 29 or [30] 54 wherein the granular particles or dried granules are extruded.

33. (Amended) A composition according to [any one of claims] claim 29 or 54 [to 31] wherein the granular particles or dried granules have a diameter of from 0.3 to 10 mm and a length that is, on average, 2 to 6 times the diameter.